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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/631,911 | 07/31/2003 | Royce S. Fishman | AGALIN 3.0-003 II | 9615 |
| 530 | 7590 | 07/08/2005 | EXAMINER | |
| LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090 | | | MITCHELL, TEENA KAY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3743 | |

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/631,911 | Applicant(s) FISHMAN ET AL. | |
| | Examiner Teena Mitchell | Art Unit 3743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/23/04; 8/9/04; 9/7/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 respectively of U.S. Patent No. 6,728,574 in view of Brooks (5,846,556). The method steps of claims 1 and 9 would have been obvious because they would have resulted from the use of the device of claim 6 of patent '574; because claim 6 of patent '574 states "inhalation" it would have been obvious that the drug would be a gas and also because the claim states in the preamble "A system for pain management" the gas would inherently produce in a patient at least one effect of analgesia, anxiolysis, and anterograde amnesia. If for any reason patent claim 6 may not be readable on the specific effect, resort is had to Brooks in an inhalant for reducing stress teaches a gas, which produces analgesia (Cols. 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a gas, which produces an analgesia effect including the

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gases taught by Brooks. **With respect to claims 2 and 10 of the instant application,** Brooks teaches the specific gases of claim 2 of the instant application (Cols. 1 and 2). With respect to the limitations of, "...immediately prior to, during and immediately after said activating of said atrial defibrillation device it would have been obvious to one of ordinary skill in the art at the time the invention was made because the pain control would need to be maintained prior to, during and after the defibrillation to ensure patient comfort. **With respect to claims 3, 4, 8, 11, 12, and 16,** it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the specific gas mixture, as different users would require different mixtures in order to provide the ideal analgesia effect, because individual users are all different and what may work for one person may not work for another person (criteria such as age, medical condition, weight, and reaction to specific drugs all would be critical in arriving at the specific gas mixture for an individual user). **With respect to claims 5 and 13 of the instant application,** the limitations can be found in claim 6 lines 19-24, with respect to the gas being delivered immediately prior to said patient's activating of said atrial fibrillation implantable cardioverter defibrillator it would have been obvious to one of ordinary skill in the art at the time the invention was made to delivery the gas prior to activating the fibrillation device in order to allow the gas enough time to provide an analgesia effect. **With respect to claims 6, 7, 14 and 15 of the instant application,** arriving at the claimed time range of delivery of the medical gas would have been obvious to one of ordinary skill in the art because different users may require a longer or shorter time range for the gas to provide the analgesia effect and therefore the time period would be

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different for different users (criteria such as age, medical condition, weight, and reaction to specific drugs all would be critical in arriving at the specific gas mixture for an individual user) however, one would not want to wait too long after delivery of the gas to activate the defibrillation device to ensure proper analgesia effect is provided.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Venin discloses a defibrillator 4,360,026.

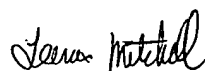
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Teena Mitchell". The signature is written in a cursive, flowing style.

Teena Mitchell
Examiner
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April 29, 2005